

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte EDDIE K. DANIELS
and NEAL E. WOOLLEN

Appeal No. 94-2208
Application 07/756,346¹

REMAND TO THE EXAMINER

Before WILLIAM F. SMITH, GRON, and PAK, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

¹ Application for patent filed September 6, 1991.

REMAND TO THE EXAMINER

We remand this application to the examiner to consider the following issues and take appropriate action.

The following claims are representative of the subject matter on appeal:

9. A subunit vaccine against Chlamydia infection comprising: (1) an essentially pure polypeptide fraction of Chlamydia psittaci strain DD-34, wherein said fraction comprises a polypeptide having a molecular weight of about 96 kilodaltons and optionally other polypeptides having molecular weights ranging from about 40 to 140 kilodaltons; and (2) a pharmaceutically acceptable carrier.

11. The vaccine of Claim 9 consisting essentially of said 96 kilodalton polypeptide.

12. A subunit vaccine against Chlamydia infection comprising polypeptides of Chlamydia psittaci strain DD-34, wherein said polypeptides are reactive with antibody secreted by hybridoma ATTC No. HB10861.

13. A method of immunizing a subject against Chlamydia comprising administering an effective amount of the vaccine of Claim 9.

A

Claims 9 through 16 are rejected at pages 3-6 of the Examiner's Answer (Paper No. 8, mailed April 30, 1993) under 35 U.S.C. § 112, first paragraph, as "lacking sufficient description or enablement." The written description requirement of this section of the statute is separate and apart from the enablement requirement of this section of the

statute. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991)(“the severability of [the ‘written description’ requirement of the first paragraph of § 112] from [the] enablement (‘make and use’) provision [of this section of the statute] was recognized by this court’s predecessor, the Court of Customs and Patent Appeals, as early as In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967)”). As explained in Vas-Cath at 1563-64, 19 USPQ2d at 1117, the purpose of the “written description” requirement is that “the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the “written description” inquiry, whatever is now claimed.”

In reviewing the statement of the rejection set forth in this portion of the Examiner’s Answer, we do not find any analysis from the examiner concerning the “written description” requirement of this section of the statute. Rather, the examiner has focussed on the enablement requirement of this section of the statute.

Upon return of the application, the examiner should review the rejection of claims 9 through 16 under 35 U.S.C. § 112, first paragraph, and determine whether the “written description” requirement of this section of the statute is involved. If so, the examiner should set forth a new statement of the rejection which explains in a clearer manner how that requirement is involved. Alternatively, if the written description requirement is not involved, the examiner should redraft the rejection in an appropriate manner.

B

To the extent that the rejection discussed above is based upon the enablement requirement of 35 U.S.C. § 112, first paragraph, our review of the record leads us to conclude that there are additional facts which the examiner should take into account. As apparent from the claims reproduced above, the invention on appeal involves a subunit vaccine against Chlamydia infection which comprises a polypeptide fraction of Chlamydia psittaci strain DD-34 containing, at a minimum, a polypeptide having a molecular weight of about 96 kilodaltons. The subunit vaccine may optionally contain other peptides having molecular weights ranging from about 40 to about 140 kilodaltons. As explained in the first paragraph of page 8 of the specification:

The high degree of antigenicity and cross reactivity of these polypeptides gives evidence of their ability to stimulate a strong immune response when purified and mixed with a suitable adjuvant. Since this is a subunit vaccine it could be useful in several species of animals, and against several different biovars of chlamydia, without the delayed type hypersensitivity reaction or anamnestic responses reported with whole organism vaccines.

The first paragraph of Example 9 of the present specification which appears at page 18 of the specification reads as follows:

The polypeptides used in the vaccine trials were isolated by sodium dodecyl sulfate polyacrylamide gel electrophoresis. Polypeptides ranging from a 40 to 140 kilodaltons of strain DD-34 were excised from the sodium dodecyl sulfate polyacrylamide gel electrophoresis, electroeluted and vacuum desiccated at room temperature to a reading of 446 on the dryness scale. These polypeptides were selected to provide support and adhesion for the antigenic 96 kilodalton polypeptide. The high degree of antigenicity

and cross-reactivity of this polypeptide gives evidence of its ability to stimulate a strong immune response when purified and mixed with a suitable adjuvant. These polypeptides were rehydrated with RIBI adjuvant, MPL + TDM + CWS to make the test vaccine.

As seen from these two passages, the present specification indicates that the polypeptides of the present invention will stimulate a so-called “strong immune response” or serve as a “vaccine” when accompanied by an appropriate adjuvant. The claims on appeal do not require the use of an adjuvant.

Upon return of the application, the examiner should consider whether the original disclosure of this application enables claims of the scope submitted, i.e., the use of any or all of the present polypeptides as a “vaccine” without the use of an adjuvant.

C

At the time the Appeal Brief was filed, claims 9 through 16 stood rejected under 35 U.S.C. §§ 102(a)/103 over a reference to Anderson. In responding to this rejection at pages 8-9 of the Appeal Brief, appellants relied upon a declaration filed under 37 CFR § 1.132 which accompanied the Appeal Brief. While it is not entirely clear whether the examiner entered the declaration, see, e.g., page 2 of the Examiner’s Answer (“the . . . declaration under 37 C.F.R. 1.132 . . . has been reviewed, but not considered . . .”), the

² It is not clear how one can review a declaration but not consider it. By this statement we take the examiner to mean the declaration was not entered. This is consistent with a handwritten notation on the upper left-hand corner of the file copy of this

rejection over Anderson was maintained. The rejection over Anderson was also maintained in the Supplemental Examiner's Answer mailed September 20, 1993 (Paper No. 10). However, in the Second Supplemental Examiner's Answer mailed December 16, 1993 (Paper No. 12) the examiner states at page 2 that "the rejection of claims 9-16 . . . over Anderson . . . is withdrawn in view of the Appellant's arguments." That Supplemental Answer was in response to a Supplemental Reply Brief filed October 7, 1993 (Paper No. 11) which does not mention Anderson by name. Nor is it clear that the arguments presented therein were specific to Anderson.

Upon return of the application, the examiner should clarify the record and state precisely why the rejection over Anderson was withdrawn. For example, did the examiner reconsider his decision not to enter the declaration and rely upon that submission in making this new decision?

declaration which says "Do not enter" followed by the date and initials of the examiner.

D

At page 6 of the Examiner's Answer, in setting forth the rejection of claims 9 through 16 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Seki and Tan, the examiner refers to section 21 of the Final Rejection. Therein, the examiner determined that the 96 kDa surface/exposed antigen of C. psittaci described in Seki "appears to be the same antigen as that of the instant claims." The examiner explains that the differences in molecular mass are expected. This finding is consistent with the last paragraph at page 7 of the specification which states that "[i]t should be noted, however, that the molecular weights disclosed herein are not to be interpreted as absolute values."

Be that as it may, it is not apparent apart from the similarity in molecular weight, on what basis the examiner determined the two antigens to be the same. The claims on appeal are directed to polypeptides obtained from Chlamydia psittaci strain DD-34. That strain was not used in Seki. Appellants raise this issue at page 11 of the Appeal Brief, setting forth three specific reasons why the polypeptide of Seki is different from that of the present invention. The examiner did not respond to these three substantive reasons in the Examiner's Answer. Furthermore, appellants rely upon passages from two references of record in support of their position at page 12 of the Appeal Brief. The examiner did not respond to this position in the Examiner's Answer.

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Upon return of the application, the examiner should review the pending rejection based upon the combined disclosures of Seki and Tan taking into account all of the arguments presented by appellants. If the rejection is maintained, the examiner should provide a more complete explanation as to why the 90 kDa polypeptide of Seki relied upon is necessarily the same as the 96 kDa protein required by the claims on appeal.

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01(d). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMAND

William F. Smith
Administrative Patent Judge

Teddy S. Gron
Administrative Patent Judge

Chung K. Pak
Administrative Patent Judge

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